510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of Safe Medical Devices Act (SMDA) and 21 CFR 807.92.

5.1 510(k) Number: K123130

SEP 17 2013

5.2 Applicant Information:

Date Prepared: September 25th, 2012

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5.3 Device Information:

Classification: DXN /Class II/870.1130
Trade Name: HRVWatch Wrist Monitor
Common Name: Non-invasive blood pressure meter system
Classification Name: Noninvasive blood pressure measurement system

5.4 Predicate Devices:

The Aneroid Mercury Sphygmomanometer K990638
The KD-788 Wrist Measurement Electronic Blood Pressure Monitor K052450
The Philips Pagewriter Touch Cardiograph K020708
The Portable ANSiscope K071188
The ReadMyHeart - Model RMHI3 K050620

5.5 Device Description:

The non-invasive blood pressure measuring system HRVWatch Wrist Monitor measures blood pressures (BP) (systolic pressure SYS and diastolic pressure DIA)

and heart rate (HR), using the oscillometric method commonly employed by electronic blood pressure meters. In addition, the device utilizes piezo-electrical sensors embedded in the cuff to obtain detailed radial arterial waveforms. The 5-minute continuous waveform recording allows the device to detect and report irregular heartbeats. Heart rate variability (HRV) parameters are also obtained by time- and frequency-domain analyses of peak-to-peak intervals. The main body of the device has the full functions of testing, display, and data storage. A mini-USB port is provided for connection and data download to a PC. A device-specific software, HRVWatch Manager, is included in the product package for database management and report printing running on a Windows-based PC. HRVWatch Wrist Monitor is intended to provide only patient parameter measurements and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

5.6 Intended Use:

Non-invasive measurement of systolic pressure (SYS), diastolic pressure (DIA), heart rate (HR), heart rate variability (HRV), and irregular heartbeats (IrrHB) for professionals at office or patients at home under the supervision of a trained professional. The device is not intended for ambulatory use. The device is designed for wearing on the left wrist only. The device provides a HRV parameter which is only mathematical analysis and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

5.7 Comparison to Predicate Device(s):

(i) HRVWatch conforms to ANSI/AAMI SP10 (confirmed by in-vitro and human clinical studies) and is substantially equivalent to the predicate devices of manual mercury sphygmomanometers for the measurement of systolic and diastolic pressures.
(ii) HRVWatch employs the oscillometric method for the measurement of systolic pressure, diastolic pressure, and heart rate and is substantially equivalent to the predicate devices of wrist-worn automatic electronic BP meters.
(iii) HRVWatch employs piezo-electrical sensors embedded in the cuff to measure radial pulse waveforms. From the 5-minute continuous pulse waveforms, peak-to-peak intervals are obtained. Peak intervals greater than 4 standard deviations are reported as irregular heartbeats. Heart rate variability (HRV) parameters are then calculated by time-domain and frequency-domain analyses. The data acquisition and analytical steps follow the guideline listed in 1996 HRV

International Standard. Confirmed by in-vitro and human clinical studies, HRVWatch is substantially equivalent to the predicate devices of electrocardiograph HRV analyzers for the measurements of HRV and irregular heartbeats.

5.8 Performance Summary (Bench and Clinical):

HRVWatch Wrist Monitor has been tested extensively by both in-vitro (bench) and human clinical studies. The test results show that HRVWatch Wrist Monitor is in compliance with the following international standards:

(i) FDA "Noninvasive blood pressure meter submission guide" (March 10, 1997)

(ii) ANSI/AAMI SP10-1992 Electronic or Automatic Sphygmomanometers

(iii) EN60601-1: 1990 (including Amendments A1 (1993) , A2 (1995)) Medical electrical equipment. General requirements for safety

(iv) IEC 60601-1: 1988 (including Amendment A1(1991) and A2 (1995)) Medical electrical equipment (this standard covers EMC safety)

(v) ISO 13485:2003 Medical Devices

(vi) 1996 Heart Rate Variability International Standard

5.9 Discussion of Clinical Test

(i) A total of 88 subjects were recruited for the human clinical study

(ii) Among the total, 10 subjects participated in the intra-device variability test, all in the SP10 BP test, and 50 subjects in the heart rate, heart rate variability, and irregular heartbeats test

(iii) Tests were conducted comparing HRVWatch to a manual mercury sphygmomanometer for measurement of BP and to an ECG for measurements of heart rate, heart rate variability, and irregular heartbeats

(iv) The clinical test results showed HRVWatch to be safe for its intended use and substantially equivalent to the predicate devices for technical designs, functions, and data accuracy

5.10 Conclusions:

After extensive bench and clinical performance tests, HRVWatch was shown to be safe in use and substantially equivalent to the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 17, 2013

Taiwan Scientific Corporation
c/o Dr. Dehchuan Sun
General Manager
10 F, 88-4, Ming-Chiuan Rd.
Shin-Dian District
New Taipei 23141
TAIWAN

Re: K123130
Trade/Device Name: HRVWatch Wrist Monitor
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: August 12, 2013
Received: August 19, 2013

Dear Dr. Sun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Indication for Use

510(k) Number (if known): K123130

Device Name: HRVWatch Wrist Monitor

Indications for Use: Non-invasive measurement of systolic pressure (SYS), diastolic pressure (DIA), heart rate (HR), heart rate variability (HRV), and irregular heartbeats (IrrHB) for professionals at office or patients at home under the supervision of a trained professional. The device is not intended for ambulatory use. The device is designed for wearing on the left wrist only. The device provides a HRV parameter which is only mathematical analysis and is not intended to produce any interpretation of those measurements or any kind of diagnosis.

Prescription Use ■ (Part 21 CFR 801 Subpart D) AND Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.09.17 13:44:00 -04'00'